1.0 **Purpose:**
The purpose of this Standard Operating Practice is to establish guidelines for the ECU University & Medical Center Institutional Review Boards (IRBs) when utilizing a primary and secondary reviewer system in proposed and ongoing human research activities.

2.0 **Reviews Affected:**
All human research submissions for consideration by the full IRB or the IRB Chairperson (or designee).

3.0 **SOP:**
All proposed or on-going human research activities requiring review by the convened UMCIRB will receive preliminary review by an IRB member(s) with the appropriate experience and/or expertise who serves as a Primary or Secondary Reviewer during the IRB deliberations. The IRB Chairperson (or designee) will serve as the Primary Reviewer for all proposed research submitted for exempt certification and all proposed or on-going human research activities that qualify for expedited review, including Continuing Review Reports, Amendment Requests, and Reportable Events (deviations, unanticipated problems, sponsor suspensions, etc.).

4.0 **Definitions:**
4.1 **Initial Review:** IRB review of human research activities by the convened full board or expedited review procedures.

4.2 **Continuation Review:** Review of on-going, previously approved human research activities, conducted with a primary reviewer.

4.3 **Amendment Request:** Request to revise on-going, currently approved human research activities conducted with a primary reviewer.

4.4 **Deviation Reports:** Reports that describe how IRB approved processes, procedures, interventions, interactions, data collection methods or actual data collected have been changed without prior IRB review and approval; conducted by a primary reviewer.

4.5 **Unanticipated problems involving risks to participants or others:** Reported events for currently or previously approved research that are unexpected, related or possibly related to the research and suggest that the research places participants or others at greater risk of harm than previously known or recognized; requires full board review with a primary reviewer.

4.6 **Primary / Secondary Reviewers:** IRB members assigned to review research materials for which they have specialized knowledge and/or are within their areas of expertise and if requires full review, leads IRB deliberations.
5.0 **Responsibilities**

5.1 **Authority of the IRB Chairperson (or designee) when serving as primary reviewer:** The IRB Chairperson (or designee) when serving as primary reviewer for expedited or exempt submissions has the authority to approve, or require modifications to expedited submissions or request additional information to clarify whether an exempt proposal meets the federal criteria for exemption certification. The Chairperson does not have the authority to disapprove proposed or expedited submissions but must refer these for consideration by the full IRB.

5.2 **Authority of Primary and Secondary Reviewers at full IRB meetings:**

5.2.1 Have the authority to make recommendations to the full convened, IRB.

5.2.1.1 These recommendations can be accepted as presented, modified, or rejected by a motion and passed by a majority.

5.2.2 Have the authority to vote on the final determinations of those recommendations.

5.3 **Ad Hoc and Continuing Consultants:** Ad Hoc and Continuing Consultants’ roles are similar to Primary Reviewers with the same authority to make recommendations. However, consultants do not have the authority to vote on the final determinations of those recommendations.

6.0 **Revision History:**

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